

REMARKS

Status of the claims

Claims 10-20 are currently pending in this application. In the present response, claims 10-12, 14-17, and 19-20 have been cancelled, without prejudice; claims 13 and 18 have been amended, and claims 21 and 22 have been added. Thus, upon entry of the amendment, claims 13, 18, 21 and 22 are presented for consideration.

Support for the Claim Amendments

Support for amendments to the claims can be found in the specification, in general, as well as deposit accession no. BP-7790, with the International Patent Organism Depository. In particular, support can be found, *inter alia*, in Example 1, page 6, lines 3-10, in Examples 2-9; and Figures 1, 3, 5, 7, 9, 11, and 13-16. Support for new claims drawn to symptoms of rheumatoid arthritis can be found in Example 3, lines 25-27, Examples 5-9, Figures 5, 7, and 9.

Issues regarding the Specification

The Patent Office objects to the specification for allegedly not having adequate information for ATCC accession No. BP-7790. Applicant herewith submits a declaration under 37 C.F.R. §1.132 setting forth the terms for accepting the deposit with an International Depository Authority and a chain of custody of the deposited organism by a person in a position to know. Moreover, the specification has been amended to recite the date of the deposit and the complete name and address of the depository.

Rejections under 35 U.S.C. §101

The Patent Office alleges that claims 12 and 14 remain rejected and claims 10, 11, 15-17, 19, and 20 are rejected under 35 U.S.C. §101 for claiming an invention directed to non-statutory subject matter. Applicant respectfully submits that the claims are not directed to non-statutory subject matter; however, in order to expedite prosecution of the instant application, Applicant cancels claims 10-12, 15-17, and 19-20, without prejudice.

Rejections under 35 U.S.C. §112, first paragraph

The Patent Office rejects claims 10-20 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Office Action alleges that claims 13 and 18 recite the limitation of "ATCC accession No. BP-7790" which lacks written description in the application as originally filed. It is noted that under 37 C.F.R. 1.804, whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made at any time before filing the application for patent or, subject to §1.809, during pendency of the application for patent. Applicant respectfully submits that the biological material, the SKG strain of mice, is specifically referred to in the application as filed. Accordingly, reference to material "deposited as accession no. FERM BP-7790 with the International Patent Organism Depository," in light of 37 C.F.R. §§1.804 and 1.809, is sufficiently described in the application as filed.

The Patent Office further alleges that the deposit information of SKG embryos provided 2/7/02, paper number 18, does not fulfill the deposit requirements. The Patent Office alleges on page 5, lines 13-19, of the Office Action that Applicant has not provided a declaration indicating that the chain of custody was maintained since the time of filing, or provide any indication how the embryos deposited correlate to the mice disclosed in the specification. Applicant submits herewith a declaration setting forth the chain of custody of the deposited organism. Moreover, Applicant submits that the embryos that were deposited are mice homozygous for the ability to develop arthritis. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 13 and 18 based upon 35 U.S.C. §112, first paragraph.

The Patent Office rejects claims 10, 15, and 17, filed 5/17/00, 2/7/02, and 2/7/02, respectively, under 35 U.S.C. §112, first paragraph, for allegedly containing new matter. Applicant respectfully disagrees; however, in order to expedite the prosecution of the instant application, Applicant had cancelled claims 10, 15, and 17, without prejudice. Amended claim 18 is similar to cancelled claim 15. Applicant respectfully submits that support for amended claim 18 can be found at least at page 4, lines 15-18, and page 5, lines 14-17. Accordingly, no new matter is introduced by amended claim 18.

Rejections under 35 U.S.C. §112, second paragraph

Claims 10-20 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention (see page 7, line 4, to page 8, line 14, of the Office Action).

The Patent Office alleges that the metes and bounds of the "mouse strain" claimed cannot be determined. Applicant respectfully traverses this rejection and submits that amended claims 13 and 18 recite that the mouse strain that which has been deposited with the International Depository Authority and is homozygous for the genes causing the natural onset of rheumatoid arthritis.

The Patent Office alleges that claims 12, 15, and 17 are unclear because the phrase "mouse strain from BALB/c mice" does not clearly state the "strain" is not BALB/c, the "strain" has a different genotype or phenotype than the BALB/c strain or that the "strain" is derived from the BALB/c strain. Applicant submits that this rejection is moot as to cancelled claims 12, 15, and 17. The Patent Office further alleges that the metes and bounds of what Applicant considers "natural onset" of rheumatoid arthritis cannot be determined. Applicant respectfully disagrees. One of skill in the art would understand from the specification and the generally accepted meaning of the term "natural" that what is contemplated is an organism that develops rheumatoid arthritis without needing to be induced to develop rheumatoid arthritis, such as inducing arthritis using type II collagen in mice. The introduction of type II collagen to the organism is an outside event and, thus, the arthritis that the organism develops would not be "natural."

The Patent Office alleges that the phrase "a mouse from a mouse strain" (claim 13) does not clearly state the "mouse" is not the same as the "mouse strain", the "mouse" has a different genotype or phenotype than the "mouse strain" or that the "mouse" is derived from the "mouse strain." Applicant respectfully submits that claim 13 has been amended to replace the phrase "a mouse from a mouse strain" with a phrase "a mouse which is derived from a mouse strain." In other words, the claimed mouse comprises those that have the same genotype and/or phenotype as those deposited with the International Depository Authority. This amendment clarifies the phrase and, thus, obviates the rejection.

The Patent Office alleges that the phrase "mouse strain from an embryo" (claim 18) is unclear because "the mouse strain" does not come "from an embryo." Applicant respectfully submits that in amended claim 18, it is clear that the method of the invention can produce the mouse strain deposited with the International Depository Authority.

The Patent Office alleges that claims 14, 16, and 19 are unclear for containing the phrase "wherein the rheumatoid arthritis represents one or more symptoms selected from..." The Patent Office further alleges that the metes and bounds of the mice being mated in claims 15 and 17 are unclear. Furthermore, the Office alleges that the metes and bounds of a "closed colony" cannot be envisioned. Applicant respectfully submits that the cancellation of these claims renders the rejection moot as to these claims. To the extent that similar rejections may be raised against amended claim 18, Applicant provides the following reasons for the patentability of these claims.

Amended claim 18 recites "(a) repeated mating between mice in a maintained colony to produce offspring; and (b) screening the offspring for the trait of developing natural onset of rheumatoid arthritis." Applicant respectfully directs Patent Office to the specification (pg. 4, lines 15-18), where it stated that "the mouse of the invention can be produced by mating between SKG strain of mice or by mating them with other suitable strains of mice and selecting the obtained mice for those having the characteristics described above." Accordingly, the method of the instant invention contemplates that the "mating" of mice (regardless of genotype) in a colony is continually repeated among the colony members (an artificial condition) and the offsprings that develop rheumatoid arthritis are selected.

The Patent Office alleges that the phrase "mouse strain from an embryo" (claim 18) is unclear. Applicant submits that amended claim 18 obviates this rejection.

Claim Rejection under 35 U.S.C. §102

Claims 12, 14-17, 19, and 20 are rejected under 102(b) for allegedly being anticipated by Nordling of record (1992, Arthritis and Rheumatism, Vol. 35, pg. 717-722). Claims 12, 14-17, 19, and 20 are also rejected under 102(e) for allegedly being anticipated by Yamanaka et al. (US Patent 4,950,741). Applicant respectfully disagrees with the Patent Office; however, claims 12, 14-17, 19, and 20 are cancelled, thus obviating this rejection.

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Should the Patent Office apply these references to amended claim 18, Applicant submits that neither Nordling nor Yamanaka teaches repeated matings between mice in a maintained colony and screening the offsprings for rheumatoid arthritis.

As evidence of the patentability of the present invention, it should be noted that BALB/c mice were introduced in 1913 and, since then, have been used extensively in research; however, prior to Applicant's disclosure, there has been no report of a BALB/c mouse that, without being induced, will develop rheumatoid arthritis in the normal progression of its life ("natural onset" of rheumatoid arthritis).

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. §102.

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CONCLUSION

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Applicant respectfully requests that the Examiner reconsider the application and claims in light of the foregoing reasons and amendments and respectfully submits that the claims are in condition for allowance.

If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues and to work with the Examiner toward placing the application in condition for allowance.

The response was initially due January 17, 2003. A Petition for a Three-month Extension of Time, up to and including April 17, 2003, with the appropriate fee is submitted herewith. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 4/17/03

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